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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/014,670	12/14/2001	Agathe Subtil	216907US0X 4884		
22850 7590 09/09/2005 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER		
			FORD, VANESSA L		
			ART UNIT	PAPER NUMBER	
	·		1645		
			DATE MAILED: 09/09/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)	
10/014,670	SUBTIL ET AL.	
Examiner	Art Unit	
Vanessa L. Ford	1645	

Before the Filing of an Appeal Brief	5	Art Unit	T - '				
Before the Finning of all Appear Brief	Examiner						
•	Vanessa L. Ford	1645					
The MAILING DATE of this communication appe	ars on the cover sheet with the c	orrespondence add	ress				
THE REPLY FILED 4/12/2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.							
1. The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:							
	a) The period for reply expiresmonths from the mailing date of the final rejection.						
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO							
MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f)	MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).						
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL							
2. The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 27 June 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). AMENDMENTS							
3. The proposed amendment(s) filed after a final rejection,			pecause				
(a) They raise new issues that would require further co		TE below);					
(b) They raise the issue of new matter (see NOTE belo		ducing or cimplifying	the incurs for				
(c) ☐ They are not deemed to place the application in bet appeal; and/or	ter form for appear by materially re	ducing or simplifying	the issues for				
(d) They present additional claims without canceling a	corresponding number of finally rej	ected claims.					
NOTE: (See 37 CFR 1.116 and 41.33(a)).							
4. The amendments are not in compliance with 37 CFR 1.1		mpliant Amendment	(PTOL-324).				
5. Applicant's reply has overcome the following rejection(s)	- '						
6. Newly proposed or amended claim(s) would be a the non-allowable claim(s).							
7. 🛛 For purposes of appeal, the proposed amendment(s): a) 🗌 will not be entered, or b) 🖾 will be entered and an explanation of							
how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows:							
Claim(s) allowed: NONE.							
Claim(s) objected to: <u>NONE</u> .	•						
Claim(s) rejected: 7-10,34-37 and 44-47. Claim(s) withdrawn from consideration: 30-33 and 38-43.	•	•					
AFFIDAVIT OR OTHER EVIDENCE							
 The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good and and was not earlier presented. See 37 CFR 1.116(e). 							
9. The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary	vercome all rejections under appea	al and/or appellant fai	Is to provide a				
10. The affidavit or other evidence is entered. An explanation REQUEST FOR RECONSIDERATION/OTHER	n of the status of the claims after e	ntry is below or attac	hed.				
11. The request for reconsideration has been considered bu See Advisory attachment.	t does NOT place the application in	n condition for allowa	nce because:				
12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s).							
13. Other:							

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Advisory Attachment

1. Applicant's response filed April 12, 2005 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Finality of the Previous Office Action

3. Applicant suggests that the Office action was made final improperly and the finality of the Final Office action should be withdrawn.

It should be remembered that Applicant filed an <u>amendment</u> to the claims on June 8, 2004 after the receipt of a first action on the merits which was mailed to Applicant on February 10, 2004. The Office action mailed January 27, 2005 was <u>necessitated by Applicant's amendment</u> submitted June 8, 2004 and was properly made final. See MPEP 706.07(a).

Rejection Maintained

4. The rejection of claims 7-10, 34-37 and 44-47 under 35 U.S.C. 103(a), is maintained for the reasons set forth on pages 3-5, paragraph 4 of the Final Office Action.

The rejection is on the grounds that Demers et al teach a method of identifying polypeptides by: a) providing genes under the control of the type II secretion machinery, b) transcriptional fusion between the promoters of the type II genes and a reporter gene are constructed and introduced into wild-type gram-negative bacteria and mutants of these bacteria constitutively secrete proteins *via* the type III secretion machinery and c)

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the expression of the presence or activity of the protein product is demonstrated *via* the reporter gene (page 3). Demers et al teach that *Shigella* bacteria are gram-negative organisms that contain type III secretion machinery (page 1).

Demers et al do not teach Chlamydia polypeptides.

Graffais et al teach that *Chlamydia* polypeptides can be secreted by the type III secretion machinery and detected by techniques known in the art such as for example using cloning combined with vectors allowing expression of the Chlamydia polypeptides fused to markers (column 40).

Demers et al nor Graffais et al teach *Chlamydia* polypeptides selected from the group consisting of CPn0105, CPn0287, CPn0330, CPn0334 CPn374, CPn379, CPn705, CPn0710, CPn0711, CPn0820, CPn821, CPn1016 and CPn1022.

Kaman et al teach *Chlamydia* polypeptides from *Chlamydia pneumoniae* and *C. trachomatis* genomes (see the Title). Kalman et al teach for example, CPn0105 (CT016) which is a GcpE protein that is conserved in both the *Chlamydia pneumoniae* and *C. trachomatis* genomes (Table 1, page 5).

It would be *prima facie* obvious at the time the invention was made to identify polypeptides as taught by Kalman et al using the method of detecting polypeptides using Type III secretion machinery because Graffais et al teach that *Chlamydia* polypeptides can be secreted by the type III secretion machinery and detected by techniques known in the art such as for example using cloning combined with vectors allowing expression of the *Chlamydia* polypeptides fused to markers as demonstrated by the teachings of Demers et al. Additionally, Kalman et al teach that comparative analysis of the *Chlamydia pneumoniae* and *C. trachomatis* genomes will significantly enhance the understanding of both pathogens and identification of genes shared between the two species supports the requirement for capabilities in biological systems that have, over long-term association with mammalian cells, evolved to reduce metabolic capacities while optimizing survival, growth and transmission of these unique pathogens (page 385). It would be expected barring evidence to the contrary that *Shigella* bacteria comprising type III secretion machinery would be effective in identifying *Chlamydia* secreted proteins.

Applicant urges that Demers et al teach a method of screening for agents/compounds that change the expression of type II secretory proteins and/or that *Chlamydia* polypeptides can be secreted by the type III secretion machinery which block secretion through this pathway. Applicant urges that Graffais nor Kalman et al add anything substantive to the Demers disclosure. Applicant urges that Graffais and Kalman et al describe a large number of genes from *Chlamydia*, some of which may be secreted by the type III pathway. Applicant urges that alone or in combination with

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Demers, Graffais and Kalman et al do not provide any suggestion for the method as claimed. Applicant urges that Graffais is silent with respect to identifying secreted proteins as claimed. Applicant urges that the combination of cited publications fail to describe or suggest each and every limitation of the claimed invention.

Applicant's arguments filed April 12, 2005 have been fully considered but they are not persuasive. It is the Examiner's position that applicant argues the references individually without clearly addressing the combination of teachings. It is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention. One of ordinary skill in the art would be motivated to combine the prior art references because Demers et al teach a method of screening polypeptides using the type III secretion machinery of gram-negative bacteria. Graffais et al teach that Chlamydia polypeptides can be secreted by the type III secretion machinery and Kalman et al disclose the specific Chlamydia polypeptides that can be secreted by the type III secretion machinery of gram-negative bacteria. One of ordinary skill in the art would reasonably conclude that specific Chlamydia polypeptides can be identified by using the type III secretion machinery of gram-negative bacteria and the these polypeptides can be detected using techniques known in the art based on the combination of prior art references. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

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Status of Claims

- 5. No claims allowed.
- 6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov./. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford

Biotechnology Patent Examiner

August 31, 2005

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SUPERVISORY PATENT EXAMINES
TECHNOLOGY CENTER BY